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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/265,540	03/08/1999	CHRISTI L. PARHAM	DX0804K	4653

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EXAMINER

WEGERT, SANDRA L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 08/12/2002 25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/265,540

Applicant(s)

PARHAM ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed 30 April 2002 (Paper No. 24) has been entered. Claims 1-15 and 17-20 are canceled. Claims 21-25 were added. Claims 16 and 21-25 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections and/or Rejections

Title

The objection to the title as set forth at p. 3 of the previous Office Action (Paper No. 22, 22 Oct. 2002) is *withdrawn* in view of the amendment which introduced a new title (Paper No. 24, 30 April 2002).

Continuity Data

The objection to the specification for reciting Patent Application No.'s without Patent No.'s, as set forth at p. 3 of the previous Office Action (Paper No. 22, 22 Oct. 2002) is *withdrawn* in view of the amendment which introduced updated continuity data (Paper No. 24, 30 April 2002).

URL's

The objection to the specification because it contained browser-executable code as set forth at p. 3 of the previous Office Action (Paper No. 22, 22 Oct. 2002) is *withdrawn* in view of

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the amendment which removed all hypertext links from the disclosure (Paper No. 24, 30 April 2002).

Abstract

The objection to the specification because it did not have an Abstract, as set forth at p. 4 of the previous Office Action (Paper No. 22, 22 Oct. 2002) is *withdrawn* in view of the amendment which added an Abstract (Paper No. 24, 30 April 2002).

Claim Objections

The objection to Claim 12 because it depended from a non-elected claim, as set forth at page 3 of the previous Office Action (Paper No. 22, 22 Oct. 2002) is *withdrawn* in view of the amendment which cancelled Claim 12 (Paper No. 24, 30 April 2002).

The objection to Claims 12 and 16 because they recited or encompassed non-elected inventions, as set forth at page 4 of the previous Office Action (Paper No. 22, 22 Oct. 2002), is *withdrawn* in view of the amendment which cancelled Claim 12 and amended Claim 16 (Paper No. 24, 30 April 2002).

Claim Rejections - 35 USC § 112, second paragraph-indefiniteness.

The objection to Claim 12 for use of indefinite language, as set forth at page 4-5 of the previous Office Action (Paper No. 22, 22 Oct. 2002), is *withdrawn* in view of the amendment which cancelled Claim 12 (Paper No. 24, 30 April 2002).

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Furthermore, the objection to Claims 12-17 for reciting various fragments and variants of the polynucleotide of SEQ ID NO: 1, as set forth at pages 8-9 of the previous Office Action (Paper No. 22, 22 Oct. 2002), is *withdrawn* in view of the amendment which cancelled Claims 12-14 and 17 and amended Claim 16 (Paper No. 24, 30 April 2002).

Objections and/or Rejections

35 U.S.C. § 101/112, first paragraph-, Lack of Utility, Enablement.

Claims 16 and 21-25 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, specific and substantial asserted utility or a well-established utility. The reasons for this rejection for Claims 12-18 under 35 U.S.C. § 101 are set forth at pp. 4-8 of the previous Office Action (Paper No. 22, 22 Oct. 2002). Claims 16 and 21-25 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth in the previous Office Action (Paper No. 22, 22 Oct. 2002) one skilled in the art would not know how to use the claimed polynucleotide.

The claims are directed to polynucleotides encoding *DIRS1* polypeptide, a kit comprising the polynucleotide, and methods of recombinant expression of the peptide encoded by SEQ ID NO: 1. The specification teaches results of Southern hybridization experiments in which expression of *DIRS1* cDNA in a large number of stimulated, diseased or normal tissues was demonstrated by using cDNA inserts of tissue-specific libraries.

Applicants argue (Paper No. 24, 7 May, 2002, page 5) that the *DIRS1* receptor encoded by the claimed polynucleotide is involved in “modulation of an inflammatory function”, as asserted in the Specification (page 68, for example). Applicants have also pointed to published journal articles that allegedly demonstrate a function for the receptor encoded by the claimed polynucleotide.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons:

The claims are directed to a nucleotide that encodes a protein that possesses 28-98% sequence similarity to known receptors, such as the uncharacterized human peptide at locus 152028 of chromosome 3 (2002, NCBI Annotation Project, Accession No. XP_087367.2) and a chicken interferon receptor (1999, Reboul, et al, Accession No. AAD13669). As discussed in the previous Office Action (p. 5), no well-established utility exists for newly isolated complex biological molecules. The specification does not disclose experiments that impart a *specific* function for the polypeptide encoded by the claimed nucleotide in the context of the cell or organism. The specification does not teach the skilled artisan how to use the *DIRS1* receptor peptide for any unique or specific purpose. Applicants argue (page 5, Paper No. 24, 30 April, 2002) that the nucleotide of the instant Specification encodes an *Interleukin-20* receptor, and that homology of the disclosed polypeptide with a class of proteins *already having* utility shall impart sufficient utility on the novel polypeptide and on the polynucleotide encoding it. However, the polypeptide of the Instant Specification and the polynucleotide encoding are, as yet, unidentified

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molecules. In fact, it cannot be determined from the Specification or from the Examiner's search of the claimed polynucleotide, the exact degree of homology between *DIRS1* and *IL-20*.

Furthermore, as pointed out in the previous Office Action (Paper No. 22, 22 Oct. 2002) There is a lack of specificity according to tissue type across many kinds of tissues as well as between diseased and normal tissue. And it should be kept in mind that tissue-specific cDNA libraries are often incomplete, or preferentially perpetuate certain clones more than others (due to GC content of the insert, for example). Thus, presence or absence in a library cannot be accepted as evidence of differential expression patterns.

Claims 16 and 21-25 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The reasons for this rejection for Claims 12-18 under 35 U.S.C. § 112 are set forth at p. 9 of the previous Office Action (Paper No. 22, 22 Oct. 2002). Essentially, enablement of the *DIRS1* receptor depends on establishing a specific and substantial utility.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

8/8/02

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